

Office of Health and Science and FDA, HHS
Dockets Management Branch (HFA-305)
Docket Number 02N-0466
Food and Drug Administration
5630 Fishers Lane
Room 1061, Rockville, MD 20852

569 02 DEC -6 AM 1:08

RE: Solicitation of Public Review and Comment of Research
Protocol: A multi-center Randomized Dose Response Study
of the Safety, Clinical and Immunize Response
of Dryvax Administered to Children 2 to 5 years of Age.
Docket number 02N-0466

to whom this may concern:

It's being said that President Bush wants to have a universal vaccination of the small pox vaccine. Would you get a flu shot in the summer? No..., then why administrate the small pox vaccine if there is no small pox threat at the moment? Not only would it be expensive, but also the side effects are too great to take the chance if the virus isn't in rotation. The ring vaccination of the small pox vaccine makes more sense. Also testing this vaccine on children is not a good idea either. The children could unknowingly spread the disease and it could also effect their social development from being away from school and other children for a long period of time.

The statistics for the small pox vaccine are that 15 out of every 1 million people will get sick, and 1 or 2 of those people will die. There are 80 million people in the U.S. so that means that 4,200 people will get sick. Why have that many people get sick if there has been no wild smallpox since 1972, and it can't reappear unless in bio-terrorist warfare? In such a case that someone does get the disease then they should receive the ring vaccination which means that the person who is infected receives treatment, and then the people that interact with that person also get the vaccin, and then finally the people around them. It makes more sense because these would be the people who would have the chance to be infected.

The sample testing for the small pox vaccine would be on children between the ages of 2-5. Most likely these children will be healthy normal children, so why put them at risk for getting sick or even dying. You also must put into consideration that what mother would want to do this to her child. So if you give money to the families for letting their child be part of this then the children are going to be mainly children off of the streets who are mal-nourished and probably have other illnesses already, so that might alter the results. Also taking the children out of school or daycare for a month could cause problems with the child's social development because this is the time when they are developing social skills and needs. But the most important reason is because the children could spread the disease so easily. When they receive the vaccine it is an opened wound with the actual virus in it. Yes there is a bandage over it, but these are kids we are talking about and they can conquer ripping any kind of bandage off. So if the child touches their wound and touches their eye they can get small pox in their eye, but even worse if they touch another person they can give that person small pox, and then we will have a small pox out break.

02N-0466

C35

How can you get accurate results from only testing 40 children? That will give you a base for your study, but once this is done, if you do decide to go through with it, there must be more done before you can administer the vaccine. I don't believe that it is right to test on little children. Also if there is a want for universal vaccination so badly, but there is no actual bio-terrorist threat, then why is it wanted so badly? Does the government know something that we as a people don't? Do they want to prepare us for something, but won't tell us what it is?

Thank you for taking the time to read my letter

Sincerely,
Taryn Kuchar